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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,992	09/17/2003	James C. Kennedy	067286-0275	1971

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,992	KENNEDY ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The examiner notes the receipt of the Arguments/Remarks and Rule 130, 131, 132 affidavits received in the office on 3/13/2007. Claims 11 and 16 have been amended. Claims 11-20 are pending in the application.

Applicant's amendment of claims 11 and 16, arguments, see p2, lines 4-29, p3, lines 1-9 filed 3/13/2007, and Rule 130, 131, 132 affidavit with respect to the rejection(s) of claim(s) 11-20 under 35 U.S.C 112(1) rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejections are made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4 of U.S. Patent No. 5,079,262 ('262).

Claims 11-20 of the instant application is directed to a method of treating a genital-wart, comprising administering to a patient a compound that causes the rate-limiting step in the biosynthetic pathway to protoporphyrin IX for heme to be bypassed and that induces accumulation of protoporphyrin IX in said wart and then exposing said wart to a wavelength of light within the photoactivating spectrum of protoporphyrin IX. The application also teaches one of the compounds to be 5-aminolevulinic acid (5-ALA).

Claims 1, 3-4 of the patent '262 teach a method of treating for treating non-malignant lesion such as genital wart administering a compound such as 5-aminolevulinic acid so as to induce synthesis of protoporphyrin IX in said lesions, and exposing said lesions to light within the photoactivating spectrum (range of 350-650 nm) of said protoporphyrin IX.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent teach a method of treating genital-wart administering a compound such as 5-ALA , that induces the accumulation of protoporphyrin IX and exposing said lesions to light within the photoactivating spectrum (range of 350-650 nm) of said protoporphyrin IX.

Claims 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 7, 13 of U.S. Patent No. 5,422,093 ('093).

Claims 11-20 of the instant application is directed to a method of treating a genital-wart, comprising administering to a patient a compound that causes the rate-limiting step in the biosynthetic pathway to protoporphyrin IX for heme to be bypassed

and that induces accumulation of protoporphyrin IX in said wart and then exposing said wart to a wavelength of light within the photoactivating spectrum of protoporphyrin IX. The application also teaches one of the compounds to be 5-aminolevulinic acid (5-ALA). The instant application teaches genital wart as a non-malignant lesion.

Claims 1, 3, 7, 13 of the patent '093 teaches a method for treating or detecting in a patient rapidly growing cells that preferentially accumulate a photoactivatable porphyrin, comprising the steps of administering to said patient, or contacting said cells with, an effective amount of a precursor of protoporphyrin IX such that said cells accumulate therapeutic or detectable levels of said protoporphyrin IX, and thereafter exposing said cells to light capable of photoactivating said protoporphyrin IX. The reference teaches the precursor to be 5-ALA and the wavelength of the photoactivating light in the range of 350-640nm and the said rapidly growing cells comprise a lesion selected from the group consisting of a benign, malignant or non-malignant lesion.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent teach a method of treating a non-malignant lesion, genital-wart administering a compound such as 5-ALA , that induces the accumulation of protoporphyrin IX and exposing said lesions to light within the photoactivating spectrum (range of 350-640 nm) of said protoporphyrin IX.

Claims 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No 6,710,066 ('066).

Claims 11-20 of the instant application is directed to a method of treating a genital-wart, comprising administering to a patient a compound that causes the rate-limiting step in the biosynthetic pathway to protoporphyrin IX for heme to be bypassed and that induces accumulation of protoporphyrin IX in said wart and then exposing said wart to a wavelength of light within the photoactivating spectrum of protoporphyrin IX. The application also teaches one of the compounds to be 5-aminolevulinic acid (5-ALA). The instant application teaches genital wart as a non-malignant lesion.

Claims 1-15 of the patent '066 teaches a method for treating in a human patient a non-malignant hyperproliferative skin lesion that preferentially accumulates a photoactivatable porphyrin, comprising administering to said human patient in need thereof an effective amount of a precursor of protoporphyrin IX thereby accumulating therapeutic levels of said protoporphyrin IX, and thereafter exposing said skin lesion to light capable of photoactivating said protoporphyrin IX. The reference teaches the precursor as 5-ALA and the wavelength of light generated using an artificial light source is limited to the group of wavelengths consisting of 350 to 700 nanometers and also limited to the red and blue regions of the spectrum. The patent also teaches in the specification, genital wart to be a non-malignant lesion.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent teach a method of treating a non-malignant lesion example genital-wart administering a compound such as 5-ALA , that induces the accumulation of protoporphyrin IX and exposing said lesions to

light within the photoactivating spectrum (range of 350-640 nm) of said protoporphyrin IX.

Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-12, 14-21 of copending Application No. 10/605,826 ('826) .

Claims 11-20 of the instant application is directed to a method of treating a genital-wart, comprising administering to a patient a compound that causes the rate-limiting step in the biosynthetic pathway to protoporphyrin IX for heme to be bypassed and that induces accumulation of protoporphyrin IX in said wart and then exposing said wart to a wavelength of light within the photoactivating spectrum of protoporphyrin IX. The application also teaches one of the compounds to be 5-aminolevulinic acid (5-ALA). The instant application teaches genital wart as a non-malignant lesion.

Claims 4-12, 14-21 of copending Application '826 is directed to a method for treating in a human patient a non-malignant skin lesion that preferentially accumulates a photoactivatable porphyrin, comprising administering to said human patient in need thereof an effective amount of a precursor of protoporphyrin IX thereby accumulating therapeutic levels of said protoporphyrin IX, and thereafter exposing said skin lesion to light capable of photoactivating said protoporphyrin IX. The application teaches the precursor as 5-ALA and the wavelength of the light range is 350-640 and the light is generated from an artificial source and is limited to the red and blue regions of the spectrum.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application teach a method of treating a non-malignant lesion example genital-wart administering a compound such as 5-ALA , that induces the accumulation of protoporphyrin IX and exposing said lesions to light within the photoactivating spectrum (range of 350-640 nm) of said protoporphyrin IX.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER